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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ISAO SAKATA,
SUSUMU NAKAJIMA, and YOSHINORI NAKAE

Appeal 2010-001368
Application 10/518,814
Technology Center 1600

Decided: May 24, 2010

Before LORA M. GREEN, RICHARD M. LEBOVITZ, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

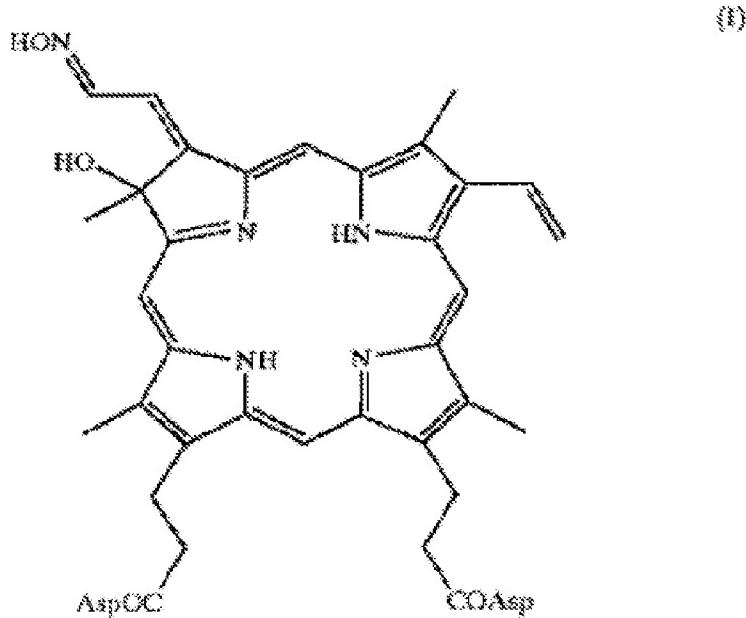
DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's rejection of claims 1, 2, 7, 8, 13, and 14. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

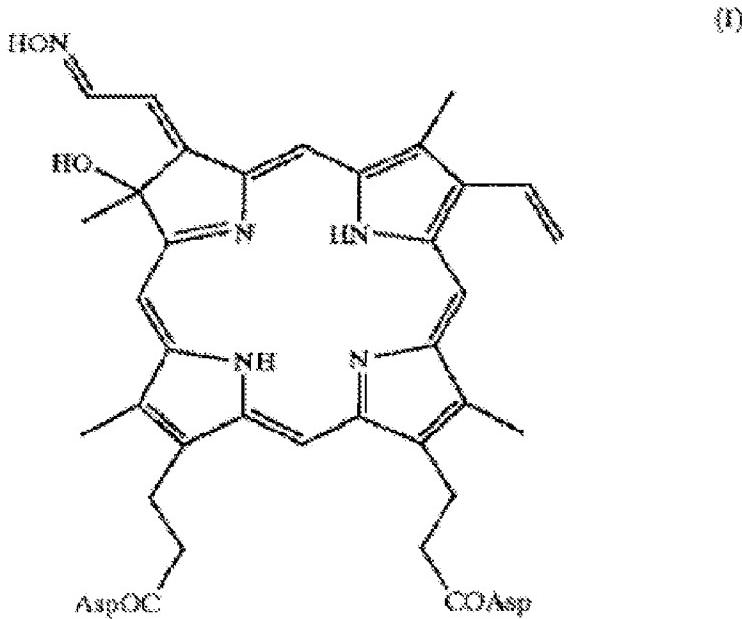
Claims 1 and 13 are representative of the claims on appeal, and read as follows:

1. A method for treating rheumatoid arthritis by photodynamic therapy, comprising administering an iminochlorine aspartic acid derivative of the following formula (I)



wherein asp represents aspartic acid residue; or a pharmaceutically acceptable salt thereof.

13. A method for determining the location of a sentinel lymph node and the presence of cancer metastasis by photodynamic therapy, comprising administering an iminochlorine aspartic acid derivative of the following formula (I)



or a pharmaceutically acceptable salt thereof
and detecting fluorescence with a fluorescent imaging system.

We affirm-in-part

PRINCIPLES OF LAW

As the Supreme Court pointed out in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” Rather, the Court stated:

[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does . . .* because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Id. at 418-419 (emphasis added); *see also id.* at 418 (requiring a determination of “whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue”) (emphasis added).

While holding that some rationale must be supplied for a conclusion of obviousness, the Supreme Court nonetheless rejected a “rigid approach” to the obviousness question, and instead emphasized that “[t]hroughout this Court’s engagement with the question of obviousness, our cases have set forth an expansive and flexible approach” *Id.* at 415. The Court also rejected the use of “rigid and mandatory formulas” as being “incompatible with our precedents.” *Id.* at 419; *see also id.* at 421 (“Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.”).

The Court thus reasoned that the analysis under 35 U.S.C. § 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418.

ISSUE (Hikida)

Does the preponderance of evidence of record support the Examiner’s conclusion that the method of claims 13 and 14 is rendered obvious by Hikida?

FINDINGS OF FACT

FF1 The Specification teaches that the invention relates to compounds for photodynamic therapy (PDT), and their use in treating vascular diseases, including rheumatoid arthritis and inflammatory keratosis. (Spec. 1.) The Specification further notes that the invention is drawn to the use of the agents for locating the sentinel lymph node and detecting cancer metastasis. (*Id.*)

FF2 The Specification teaches that PDT has been suggested for the treatment of both rheumatoid arthritis and inflammatory keratosis. (*Id.* at 2-3.)

FF3 The Specification teaches further that a “sentinel lymph node (SN) is the first lymph node to receive lymphatic drainage from a metastasized cancer.” (*Id.* at 7.) According to the Specification, lymph node metastasis of carcinoma is initiated by metastasis to the sentinel lymph node, and thus if no metastasis is found there, the assumption is that the cancer has not metastasized to other lymph nodes. (*Id.*)

FF4 The Examiner rejects claims 13 and 14 under 35 U.S.C. § 103(a) as being rendered obvious by Hikida.¹ (Ans. 5.)

FF5 The Examiner finds that Hikida teaches the iminochlorine aspartic acid derivative used in the claimed method, and also teaches that it is a photosensitizer molecule, administered in PDT in the treatment of cancer. (*Id.* at 5-6.)

FF6 The Examiner finds that Hikida teaches that the porphyrin derivative (i.e., the claimed iminochlorine aspartic acid derivative) is taken up by

¹ Hikida, US 6,063,777, issued May 16, 2000.

cancerous tissues, and is “extremely useful as a diagnostic agent for cancers and ophthalmic neurovascularization.” (*Id.* at 6.)

FF7 The Examiner notes that “Hikida does not explicitly teach the use of the iminochlorine aspartic acid derivative . . . for determining the location of a sentinel lymph node and the presence of cancer metastasis by PDT.” (*Id.*)

FF8 The Examiner concludes that it would have been obvious to do so because “Hikida teaches that these compounds are extremely useful as diagnostic agents,” and thus the ordinary artisan “would expect with a reasonable degree of certainty that the administration of said compounds would be successful in detecting the sentinel lymph node and as a result detecting the presence of metastasis.” (*Id.*)

ANALYSIS

Appellants argue that the Examiner appears to be equating the detection of cancers with detection of the sentinel lymph node. (App. Br. 6.) Appellants assert that nowhere does Hikida discuss the sentinel lymph node, nor is there any indication that the ordinary artisan would expect the claimed aspartic acid derivative compounds to accumulate in the sentinel lymph node. (*Id.* at 7.) Specifically, Appellants assert, the rejection “does not explain why the skilled artisan would reasonably expect that compounds thought to be useful as a diagnostic agent and a treatment agent for cancers and for ophthalmic vascularization would be useful in methods to detect (i) the location of a sentinel lymph node and (ii) the presence of cancer metastasis.” (*Id.*)

We conclude that the Examiner has failed to set forth a *prima facie* case that method of claims 13 and 14 are rendered obvious by Hikida for the reasons set forth above by Appellants. We are thus compelled to reverse the rejection.

CONCLUSION OF LAW

We conclude that the preponderance of evidence of record does not support the Examiner's conclusion that the method of claims 13 and 14 is rendered obvious by Hikida.

We are thus compelled to reverse the rejection of claims 13 and 14 under 35 U.S.C. § 103(a) as being rendered obvious by Hikida.

ISSUE (Hikida and Levy)

Does the preponderance of evidence of record support the Examiner's conclusion that the methods of claims 1 and 7 are rendered obvious by the combination of Hikida and Levy?

FINDINGS OF FACT

FF9 The Examiner rejects claims 1, 2, 7, and 8 under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Hikida and Levy.² (Ans. 7.)

FF10 The Examiner relies on Hikida as set forth above. (*Id.*)

FF11 Hikida teaches further that the compounds are excreted quickly from normal organs and cells, and thus it does not damage normal organs and cells and does not cause phototoxicity. (Hikida, col. 7, ll. 16-20.)

² Julia G. Levy, *Photodynamic therapy*, 13 TIBTECH 14-18 (1995).

FF12 Hikida teaches further that “the conversion of a porphyrin into a chlorin derivative allows the absorption wavelength to shift to infrared region and, as a result, it becomes possible to attain therapeutic efficacy for cancers in deep site.” (*Id.* at col. 7, ll. 21-25.)

FF13 The Examiner finds that Levy lists diseases for conditions in which there is some evidence, either clinical or preclinical, in which PDT may have efficacy, and includes psoriasis (i.e., inflammatory keratosis) and autoimmune condition (i.e., rheumatoid arthritis). (Ans. 7, citing Levy, 16, Table 1.) Specifically, Levy teaches that “Table 1 gives a partial list of such diseases for which there is some evidence, either clinical or preclinical, that PDT may have efficacy.” (Levy, 14, second column.)

FF14 The Examiner finds that Levy teaches that “[t]his apparently disparate group of diseases has common underlying features in their pathology, which provide a common ground for treatment with PDT.” (*Id.* at 7-8.)

FF15 The Examiner concludes that it would have been obvious to the ordinary artisan to treat psoriasis and rheumatoid arthritis as taught by Levy using the immunochlorine aspartic derivatives and PDT as taught by Hikida as Levy teaches that there is evidence that PDT may have some efficacy in treating those diseases.

ANALYSIS

Appellants argue that Levy only discloses the “potential indications for PDT,” and that “there is no description of the actual treatments for these diseases using photosensitizers such as the compound of formula I of the present invention.” (App. Br. 10.) Thus, Appellants assert, the ordinary

artisan would not expect that photosensitizers could be used to treat the presently claimed conditions in the absence of clinical data. (*Id.*)

Appellants assert further that Levy does not even describe compounds of formula I. (*Id.*)

Appellants assert further that Levy teaches that some photosensitizers have undesirable properties, such as clearance rate, thus suggesting to the ordinary artisan that “not all photosensitizers are suitable for all photodynamic therapy.” (*Id.* at 10-11.) Appellants assert that the ordinary artisan would understand that the statements in Levy are speculative, and the ordinary artisan “would not be inclined to try to substitute the photosensitizers described in the reference with other potential sensitizers.” (*Id.* at 11.)

Appellants’ arguments have been considered, but are not convincing. As found by the Examiner, Levy specifically teaches that there is either clinical or preclinical data supporting the use of PDT for treating certain disease conditions, such as psoriasis and rheumatoid arthritis. Hikida teaches compounds of claimed formula (I) and the advantages of their use in PDT, such as that the compounds are excreted quickly from normal organs and cells, and thus it does not damage normal organs and cells and does not cause phototoxicity. Thus, the preponderance of the evidence supports the Examiner’s determination it would have been obvious to the ordinary artisan to use the compounds of formula (I) as taught by Hikida for treating psoriasis and rheumatoid arthritis as taught by Levy. Note that all that is required is a reasonable expectation of success, not absolute predictability of success. *In re O’Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

Appellants argue that the Examiner equates psoriasis with inflammatory keratosis, but that “psoriasis is but one of a number of conditions falling within the classification ‘inflammatory keratosis.’” (App. Br. 9.) Appellants assert further that there is nothing in Levy that suggests that “photodynamic therapy would be effective for treating all of the numerous and varied conditions falling within the classification ‘inflammatory keratosis.’” (*Id.* at 10.)

As noted by Appellants, psoriasis is a condition that falls within the classification of inflammatory keratosis. Thus, the combination of Hikida and Levy, which renders obvious a method of treating psoriasis (the species), renders obvious the generic claim of a method of treating inflammatory keratosis.

CONCLUSIONS OF LAW

We conclude that the preponderance of evidence of record supports the Examiner’s conclusion that the methods of claims 1 and 7 are rendered obvious by the combination of Hikida and Levy. As Appellants did not argue dependent claims 2 and 8 separately, we affirm the rejection of claims 1, 2, 7, and 8 under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Hikida and Levy. *See* 37 C.F.R. § 41.37(c)(1)(vii).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

Appeal 2010-001368
Application 10/518,814

AFFIRMED-IN-PART

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